

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMÉRIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 11 June 2001 (11.06.01)	Applicant's or agent's file reference P161400
International application No. PCT/CA00/01078	Priority date (day/month/year) 16 September 1999 (16.09.99)
International filing date (day/month/year) 15 September 2000 (15.09.00)	
Applicant MONGOMERY, Sonya et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
12 April 2001 (12.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer A. Karkachi Telephone No.: (41-22) 338.83.38
-----------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------

Form PCT/IB/331 (July 1992)

CA0001078

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CA00/01078

Section III

Independent claim 69, due to the wording "a process for **treating mammalian blood ...for giving to a patient in a medical procedure**", "opening the door ...to **give the conditioned charge to a patient**", implies therapeutical and surgical steps to the living human body and as such no IPEA shall be required to carry out an international preliminary examination in view of Rule 67.1 (iv) PCT.

Moreover, claim 69 and claims 70 to 78 dependent therefrom have not been searched in view of Rule 39.1 (iv) PCT.

Section IV

Independent claims 1, 31 and 39 specify an apparatus/cabinet for conditioning mammalian blood with the special technical feature when compared with the closest prior art US-A-5 466 229, of a control system coupled to the door lock to lock the door before the blood charge is conditioned.

Independent claim 50 specifies a flask assembly for use in an apparatus for conditioning mammalian blood with the special technical features of a probe having three lumens and a pair of gas connectors.

The special technical feature of claims 1, 31 and 39 is nowhere to be found in claim 50, contrary to the requirement of Rule 13.2 PCT.

The two groups of claims (Group A= claims 1, 31, 39, Group B= claim 50) are therefore not so linked as to form a single general inventive concept (Rule 13.1 PCT).

Section V

US-A-5 466 229 (=D1) discloses an apparatus/cabinet for conditioning mammalian blood comprising all the features of the apparatus specified in the preamble of claims 1, 31 and 39.

The subject-matter of claims 1, 31 and 39 differs from the disclosure of D1 in that: i) the apparatus further comprises a control system operable upon closing the door to lock the door and then automatically condition the charge, deliver the conditioned charge to the receiver and unlock the door (claim 1), in that ii) the cabinet further comprises a control system coupled to the door lock that senses the condition of the door, establishes that the flask is securely positioned in the cabinet and that the door is

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CA00/01078

locked before conditioning starts (claims 31 and 39).

The above mentioned distinguishing features solve the problem of contamination and spillage of the mammalian blood and prevent contact of the blood with the operator in a non-obvious way.

The subject-matter of claims 1, 31 and 39 is therefore conforming with the requirements of Art. 33 (2), (3) PCT.

US-A-3 946 731 (=D2) discloses a flask assembly for use in an apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood, the flask assembly comprising all the features of the flask assembly specified in the preamble of claim 50.

The subject-matter of claim 50 differs from the disclosure of D2 in that the flask assembly further comprises a probe having three lumens and a pair of gas connectors. The above mentioned distinguishing features solve the problem of conditioning the mammalian blood in the flask assembly and of preparing the conditioned charge for use in a non-obvious way.

The subject-matter of claim 50 is therefore conforming with the requirements of Art. 33 (2), (3) PCT.

Claims 2-30 are dependent on claim 1, claims 32-38, 79-81 are dependent on claim 31, claims 40-49 are dependent on claim 39 and claims 51-68 are dependent on claim 50 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Section VII

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents US-A-5 466 229 (=D1) and US-A-3 946 731 (=D2) is not mentioned in the description, nor are these documents identified therein.

The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

WO 01/19318

PCT/CA00/01078

SUBSTITUTE CLAIMS

1. Apparatus for conditioning mammalian blood for subsequent use in a medical procedure, the apparatus including:

a cabinet having a secure environment and a door providing the only access to the secure environment;

an input system for transporting a blood charge from a source to the cabinet;

a flask removably contained in said secure environment and coupled to the input system to receive said charge;

stressors coupled to the cabinet and positioned for operation to create a conditioned charge in the flask;

an output system coupled to the flask and including a receiver for the conditioned charge;

the apparatus being characterized by:

a control system contained in the cabinet and operable upon closing the door to lock the door and to then automatically condition the charge and to cause the charge to move from the flask to the receiver, whereby a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure.

2. Apparatus as claimed in claim 1 in which the input system includes an input syringe operable to draw blood to form at least part of said charge, and input tubing connecting the input syringe to the flask to transport the charge into the flask.

3. Apparatus as claimed in claim 2 in which the input tubing is thermoplastic tubing, and in which the cabinet includes a first heat sealer operable to seal and sever the input tubing, whereby the input syringe can be separated from the cabinet and flask for subsequent disposal.

WO 01/19318

PCT/CA00/01078

SUBSTITUTE CLAIMS

position;

a cavity extending downwardly from the top depression within the secure environment, the cavity being adapted to receive the flask;

said cabinet being characterized by:

a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.

32. A cabinet as claimed in claim 31 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the front cavity.

33. A cabinet as claimed in claim 32 and further including a knocker mounted adjacent said mount in the front cavity and positioned for striking the receiver repetitively to break up bubbles in the conditioned charge.

34. A cabinet as claimed in claim 33 in which the knocker includes an impact tool mounted in the front cavity for striking the receiver from one side and a spring mounted in the cavity on the opposite side from the tool whereby when the tool impacts the receiver, the spring stores energy and rebounds to push the receiver towards the tool to start a new cycle.

35. A cabinet as claimed in claim 34 in which the knocker is coupled to the control system to cause the knocker to rap the receiver at a frequency of about one Hertz.

36. A cabinet as claimed in claim 31 and further including a mount in the front cavity for an output syringe which receives the conditioned charge from the flask, the syringe being held by the mount in the front cavity with the operator lowermost.

WO 01/19318

PCT/CA00/01078

SUBSTITUTE CLAIMS

37. A cabinet as claimed in claim 31 and further including an actuator in the front cavity for coupling to the operator to activate the output syringe to draw the conditioned charge into the syringe within the secure environment.
38. A cabinet as claimed in claim 31 and further including at least one heat sealer mounted for operation in the secure environment when the door is closed to sever thermoplastic tubing used to make connections to and from the flask.
39. A cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure, a blood charge being conditioned in a flask and the cabinet having:
- a front;
 - a top;
 - a door hinged for movement between an open position and a closed position in which at least a portion of the front and a portion of the top are covered by the door to create a secure environment;
 - a lock coupled to the cabinet and to the door to lock the door in the closed position;
 - a cavity extending downwardly from the top wall within the secure environment, the cavity being adapted to receive the flask;
 - said cabinet being characterized by:
 - a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.
40. A cabinet as claimed in claim 39 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the secure environment.
41. A cabinet as claimed in claim 40 and further including a knocker mounted adjacent said mount and positioned for striking the receiver repetitively to break

WO 01/19318

PCT/CA00/01078

SUBSTITUTE CLAIMS

49. A cabinet as claimed in claim 39 and further comprising an ozone generator for receiving oxygen and converting at least some of the oxygen to ozone, and an ozone delivery system for coupling to the flask when the flask is in the cavity to bubble a mixture of ozone and oxygen into the charge to condition the charge.

50. A flask assembly for use in apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood, the flask assembly including:

a flask in the form of an envelope defining a substantially enclosed volume and including a top and a bottom, the top having an access opening and an outlet;

a connector assembly coupled to said top of the flask;

said flask assembly being characterized by a probe extending from the connector assembly, through the access opening and having a top end and a leading end, the probe being sealed in the access opening and defining an input lumen for transporting the charge to the bottom of the flask, an output lumen for transporting conditioned charge from the bottom of the flask out of the flask, and a gas lumen for feeding gas into the flask to condition the charge when a charge is in the flask;

the connector assembly including outlet tubing coupled to said outlet to lead spent gas out of the flask, and inlet tubing coupled to the gas lumen;

a pair of gas connectors coupled to the platform and connected to the respective gas inlet tubing and to the gas outlet tubing to make gas connections when the flask assembly is mounted in the apparatus, whereby as the flask is engaged in the cabinet the gas connectors engage a gas supply system for conditioning said charge in the flask before removing the conditioned charge.

51. A flask assembly as claimed in claim 50 in which said enclosed volume is in the order of about 70 times the volume of the charge to be entered into the flask.

52. A flask assembly as claimed in claim 50 in which the flask is of low density

COPY

PCT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

HIRONS, Robert G.
Ridout & Maybee
150 Metcalfe Street
19th Floor
Ottawa, Ontario K2P 1P1
CANADA

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 11.12.2001

Applicant's or agent's file reference
P161400

IMPORTANT NOTIFICATION

International application No.
PCT/CA00/01078

International filing date (day/month/year)
15/09/2000

Priority date (day/month/year)
16/09/1999

Applicant
VASOGEN IRELAND LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Garry, A

Tel. +49 89 2399-2375



PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P161400	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA00/01078	International filing date (day/month/year) 15/09/2000	Priority date (day/month/year) 16/09/1999
International Patent Classification (IPC) or national classification and IPC A61J3/00		
Applicant VASOGEN IRELAND LIMITED et al.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 4 sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 12/04/2001	Date of completion of this report 11.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Louka, M Telephone No. +49 89 2399 2388 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/CA00/01078

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-19 as originally filed

Claims, No.:

4-30,31 (part),41 (part), as originally filed
42-48,52 (part),
53-81

1-3,31 (part),32-40, as received on 28/11/2001 with letter of 26/11/2001
41 (part),49-51,
52 (part)

Drawings, sheets:

1/4-4/4 as received on 01/11/2000 with letter of 18/10/2000

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/CA00/01078

listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 69-78.

because:

- ☒ the said international application, or the said claims Nos. 69-78 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 69-78.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01078

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-68, 79-81.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-68, 79-81
	No: Claims
Inventive step (IS)	Yes: Claims 1-68, 79-81
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-68, 79-81
	No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 13 DEC 2001

PCT

14

Applicant's or agent's file reference P161400	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA00/01078	International filing date (day/month/year) 15/09/2000	Priority date (day/month/year) 16/09/1999
International Patent Classification (IPC) or national classification and IPC A61J3/00		
Applicant VASOGEN IRELAND LIMITED et al.		



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 12/04/2001	Date of completion of this report 11.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Louka, M Telephone No. +49 89 2399 2388 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01078

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-19 as originally filed

Claims, No.:

4-30,31 (part),41 (part), as originally filed
42-48,52 (part),
53-81

1-3,31 (part),32-40, as received on 28/11/2001 with letter of 26/11/2001
41 (part),49-51,
52 (part)

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/CA00/01078

listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 69-78.

because:

- ☒ the said international application, or the said claims Nos. 69-78 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 69-78.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01078

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-68, 79-81.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-68, 79-81
	No: Claims
Inventive step (IS)	Yes: Claims 1-68, 79-81
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-68, 79-81
	No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CA00/01078

locked before conditioning starts (claims 31 and 39).

The above mentioned distinguishing features solve the problem of contamination and spillage of the mammalian blood and prevent contact of the blood with the operator in an non-obvious way.

The subject-matter of claims 1, 31 and 39 is therefore conforming with the requirements of Art. 33 (2), (3) PCT.

US-A-3 946 731 (=D2) discloses a flask assembly for use in an apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood, the flask assembly comprising all the features of the flask assembly specified in the preamble of claim 50.

The subject-matter of claim 50 differs from the disclosure of D2 in that the flask assembly further comprises a probe having three lumens and a pair of gas connectors. The above mentioned distinguishing features solve the problem of conditioning the mammalian blood in the flask assembly and of preparing the conditioned charge for use in an non-obvious way.

The subject-matter of claim 50 is therefore conforming with the requirements of Art. 33 (2), (3) PCT.

Claims 2-30 are dependent on claim 1, claims 32-38, 79-81 are dependent on claim 31, claims 40-49 are dependent on claim 39 and claims 51-68 are dependent on claim 50 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Section VII

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents US-A-5 466 229 (=D1) and US-A-3 946 731 (=D2) is not mentioned in the description, nor are these documents identified therein.

The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

HIRONS, Robert, G.
Ridout & Maybee
19th Floor
150 Metcalfe Street
Ottawa, Ontario K1P 1P1
CANADA

Date of mailing (day/month/year)

24 July 2001 (24.07.01)

Applicant's or agent's file reference

P161400

IMPORTANT NOTIFICATION

International application No.

PCT/CA00/01078

International filing date (day/month/year)

15 September 2000 (15.09.00)

1. The following indications appeared on record concerning:

☐

the applicant

☐

the inventor

☒

the agent

☐

the common representative

Name and Address

RICHES, MCKENZIE & HERBERT
Suite 2900
2 Bloor Street East
Toronto, Ontario M4W 3J5
Canada

State of Nationality

State of Residence

Telephone No.

416 961 5000

Facsimile No.

416 961 5081

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒

the person

☒

the name

☒

the address

☐

the nationality

☐

the residence

Name and Address

HIRONS, Robert, G.
Ridout & Maybee
19th Floor
150 Metcalfe Street
Ottawa, Ontario K1P 1P1
Canada

State of Nationality

State of Residence

Telephone No.

613 236 1995

Facsimile No.

613 236 2485

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒

the receiving Office

☐

the designated Offices concerned

☐

the International Searching Authority

☒

the elected Offices concerned

☒

the International Preliminary Examining Authority

☐

other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Marie-José Devillard

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P161400	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/CA 00/ 01078	International filing date (day/month/year) 15/09/2000	(Earliest) Priority Date (day/month/year) 16/09/1999
Applicant VASOGEN IRELAND LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 00/01078

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J3/00 A61M1/36 A61M1/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 466 229 A (KUNTZ DAVID H ET AL) 14 November 1995 (1995-11-14) column 4, line 59 -column 5, line 6; figures 1-3 column 5, line 14 -column 6, line 24 ---	1, 31, 39, 50
A	US 3 946 731 A (LICHTENSTEIN ERIC S) 30 March 1976 (1976-03-30) column 7, line 8 -column 9, line 12; figures 1,8 ---	1, 31, 39, 50
A	US 5 037 390 A (RAINES KENNETH ET AL) 6 August 1991 (1991-08-06) column 4, line 22 - line 59; figures 1,2 --- -/--	1, 31, 39, 50



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

28 November 2000

Date of mailing of the international search report

04/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Zeinstra, H

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 00/01078

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 35 11 159 A (BASE TEN SYSTEMS ELECTRONICS G) 9 October 1986 (1986-10-09) page 14, last paragraph -page 15, paragraph 2; figures 1,2 -----	1, 31, 39, 50
A	DE 43 23 295 C (HAMM MANFRED R DR) 9 February 1995 (1995-02-09) column 2, line 46 -column 4, line 66; figure 1 -----	1, 31, 39, 50

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 00/01078

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5466229	A	14-11-1995	WO	9611652 A	25-04-1996
			AU	8081994 A	06-05-1996
			EP	0786979 A	06-08-1997
US 3946731	A	30-03-1976	US	3912455 A	14-10-1975
			AU	7300574 A	11-03-1976
			CA	1034459 A	11-07-1978
			CH	612587 A	15-08-1979
			CH	594418 A	13-01-1978
			DE	2442086 A	20-03-1975
			ES	429812 A	01-09-1976
			FR	2242994 A	04-04-1975
			GB	1492386 A	16-11-1977
			IE	40006 B	14-02-1979
			JP	50072494 A	16-06-1975
			SE	7411321 A	10-03-1975
			SE	8200621 A	03-02-1982
			US	4370983 A	01-02-1983
			BE	819642 A	31-12-1974
			GB	1492387 A	16-11-1977
			IE	40007 B	14-02-1979
			ZA	7405558 A	29-10-1975
			US	3774762 A	27-11-1973
US 5037390	A	06-08-1991	NONE		
DE 3511159	A	09-10-1986	NONE		
DE 4323295	C	09-02-1995	WO	9502387 A	26-01-1995

RECEIVED BY
PAT 34 ABST

CLAIMS.

1. Apparatus for conditioning mammalian blood for subsequent use in a medical procedure, the apparatus including:
 - a cabinet having a secure environment and a door providing the only access to the secure environment;
 - an input system for transporting a blood charge from a source to the cabinet;
 - a flask removably contained in said secure environment and coupled to the input system to receive said charge;
 - stressors coupled to the cabinet and positioned for operation to create a conditioned charge in the flask;
 - an output system coupled to the flask and including a receiver for the conditioned charge; and
 - a control system contained in the cabinet and operable upon closing the door to lock the door and to then automatically condition the charge and to cause the charge to move from the flask to the receiver, whereby a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure.
2. Apparatus as claimed in claim 1 in which the input system includes an input syringe operable to draw blood to form at least part of said charge, and input tubing connecting the input syringe to the flask to transport the charge into the flask.
3. Apparatus as claimed in claim 2 in which the input tubing is thermoplastic tubing, and in which the cabinet includes a first heat sealer operable to seal and sever the input tubing, whereby the input syringe can be separated from the cabinet and flask for subsequent disposal.

position;

a cavity extending downwardly from the top depression within the secure environment, the cavity being adapted to receive the flask; and

a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.

32. A cabinet as claimed in claim 31 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the front cavity.

33. A cabinet as claimed in claim 32 and further including a knocker mounted adjacent said mount in the front cavity and positioned for striking the receiver repetitively to break up bubbles in the conditioned charge.

34. A cabinet as claimed in claim 33 in which the knocker includes an impact tool mounted in the front cavity for striking the receiver from one side and a spring mounted in the cavity on the opposite side from the tool whereby when the tool impacts the receiver, the spring stores energy and rebounds to push the receiver towards the tool to start a new cycle.

35. A cabinet as claimed in claim 34 in which the knocker is coupled to the control system to cause the knocker to rap the receiver at a frequency of about one Hertz.

36. A cabinet as claimed in claim 31 and further including a mount in the front cavity for an output syringe which receives the conditioned charge from the flask, the syringe being held by the mount in the front cavity with the operator lowermost.

37. A cabinet as claimed in claim 31 and further including an actuator in the front cavity for coupling to the operator to activate the output syringe to draw the conditioned charge into the syringe within the secure environment.

38. A cabinet as claimed in claim 31 and further including at least one heat sealer mounted for operation in the secure environment when the door is closed to sever thermoplastic tubing used to make connections to and from the flask.

39. A cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure, a blood charge being conditioned in a flask and the cabinet having:

- a front;

- a top;

- a door hinged for movement between an open position and a closed position in which at least a portion of the front and a portion of the top are covered by the door to create a secure environment;

- a lock coupled to the cabinet and to the door to lock the door in the closed position;

- a cavity extending downwardly from the top wall within the secure environment, the cavity being adapted to receive the flask; and

- a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.

40. A cabinet as claimed in claim 39 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the secure environment.

41. A cabinet as claimed in claim 40 and further including a knocker mounted adjacent said mount and positioned for striking the receiver repetitively to break

49. A cabinet as claimed in claim 39 and further comprising an ozone generator for receiving oxygen and converting at least some of the oxygen to ozone, and an ozone delivery system for coupling to the flask when the flask is in the cavity to bubble a mixture of ozone and oxygen into the charge to condition the charge.
50. A flask assembly for use in apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood, the flask assembly including:
a flask in the form of an envelope defining a substantially enclosed volume and including a top and a bottom, the top having an access opening and an outlet;
a connector assembly coupled to said top of the flask;
a probe extending from the connector assembly, through the access opening and having a top end and a leading end, the probe being sealed in the access opening and defining an input lumen for transporting the charge to the bottom of the flask, an output lumen for transporting conditioned charge from the bottom of the flask out of the flask, and a gas lumen for feeding gas into the flask to condition the charge when a charge is in the flask;
the connector assembly including outlet tubing coupled to said outlet to lead spent gas out of the flask, and inlet tubing coupled to the gas lumen;
a pair of gas connectors coupled to the platform and connected to the respective gas inlet tubing and to the gas outlet tubing to make gas connections when the flask assembly is mounted in the apparatus, whereby as the flask is engaged in the cabinet the gas connectors engage a gas supply system for conditioning said charge in the flask before removing the conditioned charge.
51. A flask assembly as claimed in claim 50 in which said enclosed volume is in the order of about 70 times the volume of the charge to be entered into the flask.
52. A flask assembly as claimed in claim 50 in which the flask is of low density



Creation date: 03-19-2004
Indexing Officer: KTRIEU - KIM TRIEU
Team: OIPEBackFileIndexing
Dossier: 10088351

Legal Date: 06-06-2002

No.	Doccode	Number of pages
1	IDS	7
2	FOR	41
3	FOR	9
4	FOR	32

Total number of pages: 89

Remarks:

Order of re-scan issued on